

EU DECLARATION OF CONFORMITY

WE THE MANUFACTURER

Name	DIAGON Kft.
Address	Baross u. 48-52. Budapest H-1047 Hungary
Single Registration Number (SRN)	HU-MF-000023582

TAKE SOLE RESPONSIBILITY FOR AND HEREBY DECLARE THAT THE PRODUCT(S)

Device category	AUXILIARY REAGENTS (HAEMOSTASIS) - OTHER
Basic UDI-DI	5992791R30KM
Country of origin	Hungary
Legal manufacturer	DIAGON Kft.
Intended Purpose	Coag Cleaner is a washing solution used for daily maintenance and cleaning of Coag Line fully automated coagulation analysers during routine use. For In Vitro Diagnostic use only.

Related device(s)	Product name	Reference number
	Coag Cleaner	h60102
	Coag Cleaner ST	h60103

MEET(S) THE PROVISIONS OF THE FOLLOWING DIRECTIVES, REGULATIONS AND STANDARDS AND COMMON SPECIFICATIONS

Regulation(s)	IVDR (EU) 2017/746 on in vitro diagnostic medical devices	
Risk Class	A <input checked="" type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D <input type="checkbox"/>	
IVDR conformity assessment route	<input checked="" type="checkbox"/> ANNEX II + ANNEX III + ANNEX IV (Class A devices excluding sterile devices)	
	<input type="checkbox"/> ANNEX II + ANNEX III + ANNEX IV + ANNEX IX (Chapter I & III) + ANNEX XI (Class A sterile devices)	
	<input type="checkbox"/> ANNEX IX (Chapter I & III, II section 4) + ANNEX IV (Class B & C devices excluding self- testing and near patient testing devices)	EU Certificate N/A
		Notified Body (NB) N/A
		NB Number N/A
	<input type="checkbox"/> ANNEX IX (Chapter I & III, II section 4 & 5.1) + ANNEX IV (Class B & C self-testing and near patient testing devices)	EU Certificate N/A
		Notified Body (NB) N/A
		NB Number N/A
<input type="checkbox"/> ANNEX IX (Chapter I & III, II including section 4.9) + ANNEX IV (Class D devices)	EU Certificate N/A	
	Notified Body (NB) N/A	
	NB Number N/A	
Directive(s)	N/A	
Standard(s)	N/A	
Common Specification(s)	N/A	

Budapest, 25 May 2022



Dr. József Kern
 Managing Director